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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,059	10/15/2001	Chris M. Farnet	3019-US	1661

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,059	FARNET ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. Claims 1-24 as originally filed in the instant specification on October 15, 2001 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

SuperGroup A. Claims 1-10 and 19-21, drawn to nucleic acids related to sequences encoding any of SEQ ID NOs: 2-34 related vectors and host cells thereof, classified in class 536, subclass 23.1.
SuperGroup B. Claims 11-13, drawn to gene cluster encoding polypeptides that produce ramoplanin and or analog thereof, classified in class 536, subclass 23.2.
SuperGroup C. Claims 14-18, drawn to polypeptides related to sequences of any of SEQ ID NOs: 2-34, classified in class 530, subclass 350.
SuperGroup D. Claims 22-24, drawn to methods of using polypeptides related to sequences of any of SEQ ID NOs: 2-34, classified in class 435, subclass 76.

3. The SuperGroups above are distinct, each from the other because of the following reasons:

The products of SuperGroups A and B are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because genes of other polyketide synthase gene clusters, which genes are not

necessarily structurally related as are the genes of SuperGroup A, can be substituted into "functional" positions of the ramoplanin gene cluster to produce ramoplanin analogs since SuperGroup B requires only a functional definition. Thus, the particular of each of ORFs 2-34 (members of SuperGroup A) are not required to meet the limitations of SuperGroup B. The subcombination has separate utility such as production of a polypeptide to modify a polyketide, which is distinct from the assembly of all the genes/proteins together that produce a whole polyketide from ketide subunits.

The products of SuperGroups A and B are related to SuperGroup C by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the enzyme product can be made by other and materially distinct processes, such as purification from a natural source; and the DNA product can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, products of SuperGroups A and B are patentably distinct from products of SuperGroup C.

The products of SuperGroups A and B are related to SuperGroup D by virtue of the fact the DNA encodes the proteins used in the methods of SuperGroup D. However, the DNA are neither used nor produced in the claimed methods, and the proteins used can be obtained for sources in the absence of isolated DNA, i.e., by purification from a natural source. Thus, the products of SuperGroups A and B are patentably distinct from the methods of SuperGroup D.

The products and methods of SuperGroups C and D are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the products can be used for a materially distinct process of using that product, such as in the production of polypeptide specific monoclonal antibodies. Thus, the products of SuperGroup C are patentably distinct from the methods of SuperGroup D..

Because these SuperGroups are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Each of the SuperGroups noted above are further divided into inventions, or Groups, as follows:

Groups 1-33, drawn to nucleic acids and related products related to SEQ ID NOs:2-34, respectively, (encoded amino acid sequences). ** The Examiner notes that some claims of SuperGroup A would be excluded in some of the noted Groups because some ORFs are excluded in Claims 2, and 6-10.
Group 34, drawn to the gene cluster. Only one Group is in SuperGroup B.
Groups 35-67, drawn to polypeptides related to SEQ ID NOs:2-34, respectively. ** The Examiner notes that some claims of SuperGroup C would be excluded in some of the noted Groups because some ORFs are excluded in Claim 15.
Groups 68-100, drawn to methods of using polypeptides related to any of SEQ ID NOs: 2-34. respectively. ** The Examiner notes that some claims of SuperGroup D would be excluded in some of the noted Groups because some ORFs are excluded in Claim 24.

5. The Groups (inventions) above are distinct, each from the other because of the following reasons:

The Groups within SuperGroup A (Groups 1-33) are related to each other as nucleic acids encoding polyketide synthase enzymes involved in polyketide biosynthesis, particularly ramoplanin biosynthesis. However, these nucleic acids encode enzymes which each have distinct functional properties catalyzing unique reactions in the biosynthetic pathway of the polyketide ramoplanin. Furthermore, these nucleic acids encode enzymes having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus among the Groups. Moreover, each of these nucleic acids encode enzymes, or pieces thereof, which can be used in a distinct process from the biosynthesis of the polyketide ramoplanin, such as in (1) domain swapping methods for use in other modular PKSs and/or peptide synthetases or in (2) hybridization techniques to identify related PKS genes in other microorganisms. Thus, members of SuperGroup A (Groups 1-33) are patentably distinct, each from the other. While these Groups of DNAs are all identically classified, to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The Groups within SuperGroup C (Groups 35-67) are related polyketide synthase or peptide synthetase enzymes, which are involved in the biosynthetic pathway of polyketides, particularly ramoplanin or simply only related by being a part of a gene cluster with several of the ORFs having undisclosed functions or functions with unclear relation to ramoplanin biosynthesis. These enzymes are distinct from each other for the reasons cited above for their encoding nucleic acids. Thus, members of SuperGroup C (Groups 35-67) are patentably distinct, each from the other. While these Groups of polypeptides are all identically classified (which

classification may be amended as functions of the polypeptides are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The methods of SuperGroup D (Groups 68-100) are related as methods of using distinct enzymes, which together can produce ramoplanin-like polyketides. The methods within each SuperGroup are distinct from every other method in the SuperGroup for the reasons cited above for the distinctness of the enzymes. Thus, members of SuperGroup D (Groups 68-100) are patentably distinct, each from the other.

Notice of Possible Rejoinder

6. The Examiner notes that if product claims in any Group in SuperGroup C are found directed to an allowable product, then process claims in any Group in SuperGroup D, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

7. A telephone call was made to Ywe Looper on September 24, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Examiner's Comments

8. Upon a cursory reading of the instant specification for purposes of restricting the subject matter of the pending claims, the Examiner noted that the sequence listing does not contain protein sequences matching all of ORFs 1-32 (as considered via sequence length alone).

a) No sequence for ORFs 2 and 3 is noted.

b) Two sequences for ORF 5 (SEQ ID NOs: 4 and 6) are noted.

c) No sequences for ORFs 13 and 14; however, SEQ ID NOs: 14 and 15 are each 4999 long (appear to have been truncated forms of ORFs 13 and 14).

d) SEQ ID NO:34 is 309 amino acids long and is perhaps a duplicate of ORF 23?

The Examiner notes that the full-length, exactly-encoding DNA sequence in SEQ ID NO:1. Thus, correction of the ORFs should be attainable without adding new matter. The Examiner strongly encourages such correction prior to a first Office action on the merits. Moreover, with any amendment to the sequence listing, the Examiner suggests submitting an alignment of SEQ ID NO:1 with all the amino acid sequences to identify clear support in the specification as originally filed.

Conclusion

9. A complete response to the instant Office action must include an election of invention to be examined. For clarity's sake, the Examiner suggests electing a SuperGroup (DNA, protein, or method of using a protein) and a SEQ ID NO of the polypeptide to elect the Group for examination (unless SuperGroup B is elected).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 24, 2003